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Sent: 9/7/2011 11:53:50 PM
To: Clark, Becki [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a906e07f1cd143b9a3c2ddab813b8140-Clark, Becki]; Winner, Darrell [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=860556f5cd0f4855839907bcc90b2c41-Winner, Darrell]; Cogliano, Vincent [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=51f2736376ac4d32bad2fe7cfef2886b-Cogliano, Vincent]
Subject: Fw: NEWS UPDATES: EPA Extension Fails To Quell Industry Concern On Acrylonitrile Assessment (Risk Policy Report)

This is getting irritating. Vince told Fensterheim that we were posting additional info so continuing to feed the media kitty is unconscionable.....just vetting....let's get this stuff that we promised up on the web asap....

Sent by EPA Wireless E-Mail Services

----- Original Message -----

From: Elizabeth Erwin

Sent: 09/07/2011 02:03 PM EDT

To: Abdel Kadry; Alan Sasso; Allen Davis; Amanda Boone-Edwards; Amanda Persad; AmandaM Evans; Andrew Hotchkiss; Andrew Kraft; Anne Grambsch; Annette Gatchett; Annie Jarabek; April Luke; Audrey Hoffer; Barbara Buckley; Barbara Glenn; Barbara Wright; Becki Clark; Belinda Hawkins; Bette Zwayer; Bob Frederick; Bob Sonawane; Brenda Carmichael; Catherine Gibbons; Charles Ris; Chon Shoaf; Chris Cubbison; Christina Powers; Christine Cai; Christine Ross; Christopher Sheth; Connie Kang; Dan Petersen; Danielle Moore; Darrell Winner; David Bussard; Deborah Segal; Debra Walsh; DebraL Jones; Denice Shaw; Doug Johns; Elizabeth Corona; Elizabeth Erwin; Eva McLanahan; Geniece Lehmann; Gina Perovich; Glenn Suter; Harlal Choudhury; Helen Knecht; Hui-Min Yang; Ila Cote; James Avery; James Ball; Jamie Strong; Janet Gamble; Jeff Frithsen; Jennifer Jinot; Jmichael Davis; John Vandenberg; Jonathan-Phillip Kaiser; Jordan Trecki; Karen Hammerstrom; Kate Guyton; Kathleen Deener; Kathleen Newhouse; Kathleen Raffaele; Kelly Serfling; Krista Christensen; Laurie Alexander; Leonid Kopylev; Lisa Vinikoor-Imler; Lucy Curtis; Lynn Flowers; Madalene Stevens; Malcolm Field; Margaret Pratt; Maria Spassova; Marian Rutigliano; Martin Gehlhaus; Mary Ross; Maureen Gwin; Michael Slimak; Michael Troyer; Michael Wright; Nagu Keshava; Norman Birchfield; Patricia Gillespie; Patricia Murphy; Paul Schlosser; Paul White; Peter Preuss; Reeder Sams; Samantha Jones; Stan Barone; Stella Spyropoulos; Sury Vulimiri; Susan Makris; Susan Rieth; Suzanne Martos; Ted Berner; Teneille Walker; Thomas Bateson; Todd Blessinger; Tom Long; Vincent Cogliano; Weihsueh Chiu

Subject: NEWS UPDATES: EPA Extension Fails To Quell Industry Concern On Acrylonitrile Assessment (Risk Policy Report)

EPA Extension Fails To Quell Industry Concern On Acrylonitrile Assessment

Posted: September 2, 2011

EPA has extended the comment deadline on its draft assessment of the risks posed by acrylonitrile, a key ingredient in plastic, but the chemical's manufacturers that first sought the extension are reiterating their calls for the agency to take a host of additional steps they are seeking that would likely soften the agency's strict risk estimate.

EPA announced in the *Federal Register* Aug. 31 that it is extending by 30 days -- until Sept. 28 -- the comment deadline on its draft Integrated Risk Information System (IRIS) assessment of acrylonitrile in response to a request from the Acrylonitrile (AN) Group, a coalition of companies that manufacture the chemical.

But the group's executive director, in a letter to EPA the same day, welcomed the extension but urged EPA to grant a host of additional requests the group is seeking before finalizing the assessment. The group "is pleased to learn that EPA is extending the comment period . . . we are disappointed that EPA has apparently rejected (or perhaps not yet addressed) the other Requests" that the group has made, Robert Fensterheim says in an Aug. 31 letter to Vincent Cogliano, head of the IRIS program. *The letter is available on InsideEPA.com. (Doc ID: 2374598)*

Among other things, the group is urging EPA to release data underlying a host of studies and models the agency relied

on, reference to other studies that may indicate less risk than EPA estimates, including a recent study by North Carolina's Science Advisory Board and an industry sponsored peer review of EPA's draft assessment. The additional information the group is seeking will allow the "public and peer reviewers to thoroughly and effectively review and comment on the draft" assessment, he says.

The group is also calling on EPA to weigh these additional data in a new revised assessment and to subject it to "an independent comprehensive peer review similar to the type of review typically provided by the National Academy of Sciences," which should include expanded charge questions, given the importance of the assessment and its potential effects on industry, Fensterheim says.

The letter is the latest from the industry group that takes issue with EPA's draft IRIS assessment for acrylonitrile, a widespread chemical used in making plastics, synthetic rubbers, surface coatings, adhesives and medical tubing. The agency released the assessment in late June after stalling the document for a year pending further review of controversial studies from the Ramazzini Institute, an Italian laboratory whose studies industry argues overestimate cancer risks.

The document released by the agency drops its previous reliance on Ramazzini studies, a move that resulted in the agency dropping the additional safety factors -- known as age dependent adjustment factors (ADAF) -- it had originally proposed to add to protect children (*Risk Policy Report*, July 7).

Despite removing the ADAFs, EPA nevertheless proposed to tighten its 20-year-old cancer and non-cancer risk estimates, and suggests a first-time reference dose (RfD), or the amount of the substance the agency believes can be ingested daily over a lifetime without adverse effects.

The risk assessment calls for an oral cancer slope factor of 5 milligrams per kilogram per day (mg/kg-day), which tightens its 1991 estimate of oral cancer risk, 5.4×10^{-1} (mg/kg/day), and a new inhalation unit risk of 2×10^{-2} milligrams per cubic meter (mg/m³), revised from the 1991 estimate of 6.8×10^{-5} micrograms per cubic meter (ug/m³).

When finalized, the assessment could be used by the agency to drive a host of new air toxics, water and cleanup standards for the chemical, which is present at several waste sites, including some on the agency's Superfund list.

But the assessment has come under fire from industry, who says that the agency has reached a different and overly conservative conclusion than other groups that have looked at the data in determining the chemical as "likely to be carcinogenic to humans," and want those other reviews at least mentioned in the draft document.

In particular, the group points to a recent risk assessment by the State of North Carolina and a 2004 contractor peer review of the agency's draft assessment for AN.

"It is inappropriate for the Agency to consider these items as unimportant 'secondary sources' as they are, in fact, scientific analyses and interpretations of the primary data," Fensterheim wrote in the Aug. 31 letter. "EPA's viewpoints on these publications should be just as important, if not more so, particularly when the reviews provide perspectives at variance with the Agency's own analysis. We are not advocating that EPA accept these interpretations, but ignoring their existence fails to provide a thorough, balanced review of all the available scientific information."

The group is further asking that the agency "Supplement the docket with the supporting data/models and other information that EPA relies on in the draft assessment so that stakeholders and peer reviewers can effectively review and comment," including data from a National Cancer Institute study that serves as the basis for the cancer estimate; messages from a researcher behind a 2005 study that serves as the basis for the non-cancer estimate; and further information on the physiologically based pharmacokinetic (PBPK) modeling used in the assessment.

Doing so, Fensterheim wrote, "ultimately serves EPA goals of 'improving transparency' and remaining 'strongly committed to scientific integrity, public involvement, rigorous independent external peer review, and full consultation' in the IRIS program," provisions laid out in the agency's August 2011 IRIS Progress Report.

The letter expands on concerns raised by the AN Group at an Aug. 10 EPA listening session on the issue in Arlington, VA. However, EPA officials at the time were vague on how they would address those questions, with Coglianò largely sidestepping using analyses and other risk assessments. But he noted that including more data that serves as the basis for the assessment that "there is something that can be said for that type of discussion."

The AN assessment is the first time Coglianò has publicly addressed questions about an IRIS assessments since EPA's newly revised IRIS process that was laid out by the agency's research chief Paul Anastas in July, and calls for more transparency.

Anastas announced July 12 that the agency is working to update its IRIS assessment process to take into account recommendations made by an NAS review of an EPA formaldehyde risk study that found flaws with the process including a lack of transparency in IRIS decisions.

As such, Anastas laid out a series of transparency measures that EPA intends to undertake in response to those criticisms, including working towards "streamlining IRIS assessment documents and more fully documenting the approach taken to assemble and evaluate the range of scientific data," according to a July 12 IRIS Progress Report.

At the Aug. 10 listening session Coglianò noted the need for the agency to better justify the data it selects when crafting IRIS assessments, but also defended the process, saying "We do not cherry pick primary literature."

However, EPA officials at the session offered few specifics in response to broad concerns raised by industry and other officials who called on the agency to better justify the data used in the AN assessment (*Risk Policy Report*, Aug. 16). --

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